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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,814	02/27/2004	John G. Babish	068911-0075	5630

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Simona A. Levi_Minzi PH.D.,JD
Mcdermott Will Emery LLP
201 S. Biscayne Boulevard, ste.2200
Miami, FL 33131

EXAMINER

KANTAMNENI, SHOBHA

ART UNIT PAPER NUMBER

1617

DATE MAILED: 10/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/789,814	BABISH ET AL.	
	Examiner	Art Unit	
	Shobha Kantamneni	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on 08/07/2006 has been entered.

Applicant's amendment is sufficient to overcome the rejection of claims 7 under 35 U.S.C. 112, second paragraph, as being indefinite.

The rejection of Claims 1-7 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-115 of copending Application No. 10/464410; the rejection of claims 4-7 as being unpatentable over claims 1-34 of copending Application No. 10/464834; the rejection of claims 1-3 as being unpatentable over claims 1-12 of copending Application No. 10/689856; unpatentable over claims 1-6 of copending Application No. 10/774048 is MAINTAINED. Note: Applicants offer to submit and accept terminal disclaimers linking any of the cited copending applications to the instant application should the instant case proceed to allowance.

The declaration provided by the applicant Dr. John G. Babish has been considered, and found persuasive to remove Kurhts (US 2004/0137096) as a prior art reference. The rejection of Claims 1-7 under 35 U.S.C. 103(a) as being unpatentable over Kuhrts is herein withdrawn.

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Claims 1-7 are examined herein.

Upon further consideration, the following new ground(s) of rejection have been made.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment with respect to new claim 7 has been fully considered but is deemed to insert new matter into the claims since the specification as originally filed does not provide support for limitation "wherein R' is selected from the group consisting of O".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or
- (2) a patent granted on an application for patent by another filed in the United States before

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the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3 is rejected under 35 U.S.C 102(e) as being anticipated by Shahlal et al. (US 6,583,322, PTO-892).

Shahlal et al. discloses compositions comprising a reduced isoalpa acid (RIAA) and isoalpa acid (IAA). Isoalpa acids include isohumulone, isocohumulone, isoadhumulone, reduced isoalpa acid disclosed therein include dihydro isoalpa acids (DHIA), and hexahydro isoalpa acids ((HHIA). See abstract; FIG.1; FIG.2; column 1, lines 14-24.; lines 60-63; column 4, lines 2-25. It is also disclosed that compositions therein which are mixtures of DHIA, and IAA remained clear liquids at all ratios between about 1 and 99 %., and comprise at least 0.1 % of the composition. See column 18, lines 15-45

Thus, Shahlal et al. anticipates instant claims 1-3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tobe (US 5,604,263, PTO-892).

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Tobe teaches a method of treating inflammatory disorder osteoporosis, comprising administering a pharmaceutical composition comprising an effective amount of one or more compounds selected from alpha acids, isoalpha acids and derivatives contained in hop extract such as isohumulone, isocohumulone, and isoadhumulone of the instant claims. See abstract; column 2, structures (IV) to (VI), lines 64-67; column 8, claim 1-4. It is also taught that isoalpha acid derivatives contained in hop extracts have a similar structure to that of prostaglandin E2, namely 5-membered ring with an unsaturated carbonyl group, and are useful for treating PGE2 mediated inflammation. It is further taught that the isoalpha acid derivatives inhibit bone resorption at a concentration of as low as 1×10^{-9} M. See column 2, line 54-column 3, line 30.

Tobe does not teach the employment of reduced isoalpha acid such as dihydro-isohumulone, dihydro-isocohumulone, and dihydro-adhumulone in the method therein.

Tobe does not expressly teach the ratio of reduced isoalpha acid to isoalpha acid compounds as about 3:1 to about 1:10.

It would have been obvious to a person of ordinary skill in the art to employ reduced isoalpha acid in the method of treating inflammatory disorder osteoporosis because Tobe teaches that compounds which has structure similar to that of prostaglandin E2 are useful in treating PGE2 mediated inflammation, and reduced isoalpha acid has a structure similar to that of prostaglandin E2, and further reduced isoalpha acid is a derivative of isoalpha acid which is used for treating inflammatory disorder. Thus, one of ordinary skill in the art at the time of

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invention would have been motivated to employ reduced isoalpha acid such as dihydro-isohumulone in combination with isoalpha acid with reasonable expectation of treating PGE2 mediated inflammation.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as effective amounts of the reduced isoalpha acid: isoalpha acid employed in the composition of Tobe, to treat osteoporosis.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the effective amounts of compounds such as reduced iso-alpha acids, and iso-alpha acids employed in the pharmaceutical compositions for methods of reducing inflammation in which the ratio of two compounds is about 3:1 to about 1:10, since the optimization of effective amounts to be administered, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re*

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Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-115 of copending Applications 11/344555, 11/344556, and 11/344557. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims of 11/344555, 11/344556, and 11/344557. Note that "A composition comprising, as a first component, a fraction derived from hops" in the copending application implies that the composition would contain iso α and reduced iso α acid. The claimed composition, and method of reducing inflammation are within the scope of the claims of the copending Application 11/344555, 11/344556, and 11/344557. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced iso α acid : iso α acid, to treat inflammation.

Claims 4-7 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-34 of copending Applications No. 11/344552, 11/344554, and 11/403034. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims. Note that, "comprising a fraction isolated or derived from hops" in the copending application implies that the pharmaceutical composition would contain isoalpa and reduced isoalpa acid. The claimed method of reducing inflammation is within the scope of the claims of the copending Application 11/344552, 11/344554, and 11/403034. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpa acid: isoalpa acid, to obtain a desired effect such as reducing inflammation.

Claims 1-3 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-31 of copending Application No. 10/789,817. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the instant claims overlaps with the stated claims of 10/789,817. Note that, "A composition comprising a fraction isolated or derived from hops" in the copending applications implies that the pharmaceutical composition would contain isoalpa and reduced isoalpa acid. The claimed composition is within the scope of the claims of the copending Application 10/789,817. It would have been obvious to a person of ordinary skill in the art at the time of invention to optimize parameters such as effective amounts of the reduced isoalpa acid : isoalpa acid, to obtain a desired effect.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D
Patent Examiner
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**SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER**